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FUJIFILM MEDICAL SYSTEMS USA, INC.

419 WEST AVENUE  
STAMFORD, CT 06902  
Telephone: 203/324-2000  
Fax: 203/353-0926

## 510(K) Summary

In accordance with the requirements of the Safe Medical Device Act, FUJIFILM Medical Systems, USA, Inc. herewith submits a 510(K) summary of safety and effectiveness for the following device.

**SUBMITTER NAME / ADDRESS:** FUJIFILM Medical Systems, USA, Inc.  
419 West Avenue  
Stamford, CT 06902

**CONTACT PERSON / TEL NO:** Frank Gianelli  
Regulatory Coordinator  
Tel No: (203) 602-3774

**DATE SUMMARY PREPARED:** October 17, 2003

**ESTABLISHMENT NO.:** 2443168

**TRADE/PROPRIETARY NAME:** Fuji Medical Dry Laser Imagers, models  
DRYPIX 7000, DRYPIX 5000, FM-DP L

**COMMON/USUAL NAME:** Medical Dry Laser Imager

**CLASSIFICATION NAME:** Medical Image Hardcopy Device

**CLASS/PANEL:** Class II, 90-LMC, 21CFR 892.2040

**PREDICATE DEVICE(S):** Agfa LR 5200 Laser Film Recorder  
Kodak DRYVIEW 8610 Laser Imager

### DEVICE DESCRIPTION:

Fuji Medical Dry Laser Imagers models DRYPIX 7000, DRYPIX 5000 and FM-DP L are image recording devices that use laser exposure and thermal development to print on medical dry imaging films the digital image data that is sent from medical diagnostic imaging modalities. Image processing is performed on the obtained digital images, and via laser exposure, and thermal development the processed images are recorded on film. The main difference between the FM-DP L device and the DRYPIX devices are image throughput. The only difference in the DRYPIX devices is that the DRYPIX 7000 is a 220 Vac version while the DRYPIX 5000 is a 110 Vac version.

### INTENDED USE:

Fuji Medical Dry Laser Imagers, models DRYPIX 7000, DRYPIX 5000 and FM-DP L are indicated for use in providing diagnostic quality medical images on film for aid in physician diagnosis, including the printing of images and associated identification information from various digital imaging source modalities, including but not limited to, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Ultrasound, Computed Radiography, Digital Radiography, Digital Mammography and Nuclear Medicine.



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**PREDICATE DEVICE AND SUBSTANTIAL EQUIVALENCE INFORMATION:**

Fuji Medical Dry Laser Imagers models DRYPIX 7000, DRYPIX 5000 and FM-DP L are considered comparable and substantially equivalent to the Agfa LR 5200 Laser Film Recorder (K012010) manufactured by Agfa Corporation and the Kodak DRYVIEW 8610 Laser Imager (K002146) manufactured by the Eastman Kodak Company.

**SAFETY INFORMATION:**

Fuji Medical Dry Laser Imagers, models DRYPIX 7000, DRYPIX 5000 and FM-DP L introduce no new safety and efficacy issues other than those already identified with the predicate devices. The results of a hazard analysis, combined with the appropriate preventive measures taken indicate that the device is of minor level of concern as per the May 29, 1998 issue of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Fuji Medical Dry Laser Imagers, models DRYPIX 7000, DRYPIX 5000 and FM-DP L comply with the following mandatory and voluntary standards:

- 21 CFR 1040.10 - Performance Standards for Light Emitting Products (Laser Products)
- Medical Electrical Equipment Part 1: General Requirements for Safety UL Standard 60601-1 (IEC 60601-1-1 included)
- Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility - Requirements and Tests: IEC 60601-1-2
- DICOM (Digital Imaging and Communications in Medicine) - Developed by the American College of Radiology and the National Electrical Manufacturers Association.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Mr. Frank Gianelli  
Regulatory Coordinator  
FUJIFILM Medical Systems, USA, Inc.  
419 West Avenue  
STAMFORD CT 06902

Re: K033377  
Trade/Device Name: Fuji Medical Dry Laser Imagers  
Models; DRYPIX 7000, DRYPIX 5000, and FM-DP L  
Regulation Number: 21 CFR 892.2040  
Regulation Name: Medical image  
hardcopy device  
Regulatory Class: II  
Product Code: 90 LMC  
Dated: October 20, 2003  
Received: October 22, 2003

Dear Mr. Gianelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

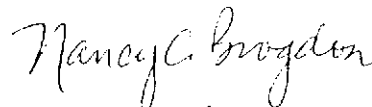
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033377Device Name : Fuji Medical Dry Laser Imagers, models DRYPIX 7000, DRYPIX 5000 and FM-DP L

Indications For Use :

Fuji Medical Dry Laser Imagers, models DRYPIX 7000, DRYPIX 5000 and FM-DP L are indicated for use in providing diagnostic quality medical images on film for aid in physician diagnosis, including the printing of images and associated identification information from various digital imaging source modalities, including but not limited to, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Ultrasound, Computed Radiography, Digital Radiography, Digital Mammography and Nuclear Medicine.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
( Per 21 CFR 801.109)OR Over-The-Counter Use ☐

Nancy C. Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

(Optional Format 1-2-96)

510(k) Number K033377